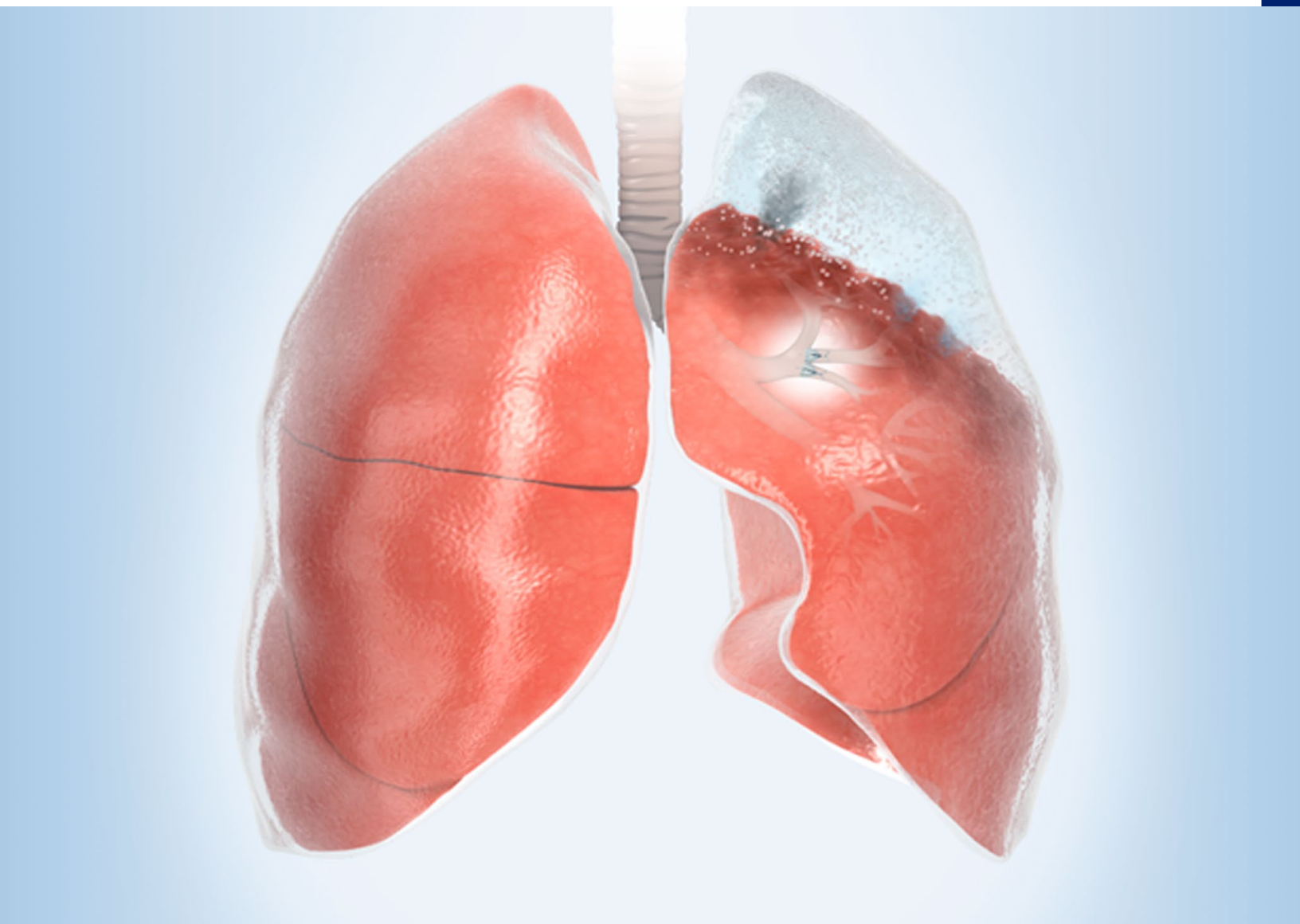
OLYMPUS

2022 Reimbursement Guide

Spiration™ Valve System

Humanitarian Use Device for Management of Air Leaks



Spiration™ Valve System for Management of Air Leaks

Introduction

Important Notice to Readers: This document is intended to help physicians, hospitals and ambulatory surgery centers better understand coding, billing, coverage policies and reimbursement methodologies for bronchial air leak valve procedures that involve Olympus bronchoscopy equipment.

The information presented here is for illustrative purposes only and does not constitute reimbursement or legal advice. The reimbursement information provided by Olympus America Inc. and/or its direct or indirect (through one or more intermediaries) parent companies, affiliates or subsidiaries (collectively, the "Olympus Group") is gathered from third-party sources and is subject to change without notice. Reimbursement rules vary widely by insurer so you should understand and comply with any specific rules that may be set by the patient's insurer. You must also understand and comply with Medicare's complex rules. It is the provider's sole responsibility to determine medical necessity and in turn identify the appropriate codes, charges, and modifiers for services rendered to submit accurate claims. It is the provider's sole responsibility to determine medical necessity and to in turn identify which CPT codes to report and to submit accurate claims. You should always consult with your local payers regarding reimbursement matters. Under no circumstances shall the Olympus Group or its employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages (whether direct, indirect, special, incidental, consequential or otherwise) that may arise from or be incurred in connection with this information or any use thereof.

Coding recommendations, coverage policies, and reimbursement rates and methodologies vary by payer and are updated frequently. Providers should review applicable payer guidelines and instructions to ensure that billing practices comply with the payer's requirements and contact the payer if they have any questions.

The American Medical Association (AMA) is responsible for development and maintenance of Current Procedural Terminology (CPT®) codes. Providers should check the complete AMA CPT reference manual and/or another authoritative source for a complete listing of all CPT codes and their descriptors. It is the provider's responsibility to report the code(s) that accurately describes the procedure(s) furnished and the patient's diagnosis. Please note that the presence of a code, or billing a particular code, is not a guarantee of payment. Reimbursement will vary for each provider based on a number of factors, including the payer, site of service, geographic location and contractual terms.

Spiration™ Valve System for Management of Air Leaks

Humanitarian Device for Use in the Control of Prolonged Air Leaks

HUD/HDE Status

A Humanitarian Use Device (HUD) is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year.

Spiration applied for and received U.S. Food and Drug Administration (FDA) designation as a HUD and received Humanitarian Device Exemption (HDE) approval for the use of its minimally invasive Spiration Valve System to control prolonged air leaks of the lung or significant air leaks that are likely to become prolonged, following lobectomy, segmentectomy and Lung Volume Reduction Surgery (LVRS). FDA approval of an HDE authorizes the applicant to market a HUD subject to certain conditions of approval.

Indication for Use

The Spiration Valve System is indicated to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy and Lung Volume Reduction Surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. The Spiration Valve System use is limited to 6 weeks per prolonged air leak.

Caution

Humanitarian Device. Authorized by Federal Law for use in the control of prolonged air leaks of the lung or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician.

- **Contraindications:** Patient is unable to tolerate a flexible bronchoscopy procedure. Allergy to latex and nickel.
- **Warnings:** Atelectasis may occur after the air leak seals and patients should be monitored for this possible complication.
- **General Precautions:** The Spiration Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis. Only use a bronchoscope with a working channel of 2.6 mm or larger. Do not use the Spiration Valve System for other than its intended use.
- **Potential Adverse Effects:** Atelectasis; Death; Infection in the tissue distal to a valve; Local airway swelling or edema at site of valve implantation; Pneumothorax.
- **For full prescribing information please see the Supporting Documentation Section of this guide.**

Spiration™ Valve System for Management of Air Leaks

Spiration Valve Procedure Overview for Air Leak

Postoperative air leaks continue to be the most common complication following lung resection surgery and a leading cause of increased hospitalization, morbidity and cost. Postoperative air leaks that are present 5–7 consecutive days following the surgery are typically classified as "prolonged" air leaks.[1] Conventional management of prolonged air leaks involves chest drainage and observation followed by more invasive treatments when leaks do not resolve.[1]

The Spiration Valve System is the only FDA approved device indicated to control prolonged air leaks of the lung following lobectomy, segmentectomy and Lung Volume Reduction Surgery (LVRS). The Spiration valves are inserted proximal to an air leak through a minimally invasive bronchoscopic procedure. Once in place the one way valve limits distal airflow. The reduction of airflow may facilitate the resolution of the air leak.

Inpatient Hospital Coding and Reimbursement

The Centers for Medicare & Medicaid Services (CMS) assigns discharges to Medicare Severity Diagnosis Related Groups (MS-DRGs) that determine inpatient reimbursement. Inpatient MS-DRG assignment and reimbursement is determined by ICD-10-PCS procedure code selection and ICD-10-CM primary and secondary diagnosis code related to the inpatient admission.

ICD-10-PCS Endobronchial Valve Procedure Codes

Hospitals use ICD-10-PCS procedure codes to describe procedures performed on inpatients. The table below identifies potential ICD-10-PCS procedure codes that may be used to describe the insertion and removal of the endobronchial valve(s). Hospitals are responsible for accurately selecting ICD-10-PCS procedure codes to describe the procedures performed during an inpatient stay.

The ICD-10-PCS procedure codes listed in this table are not intended to be an exhaustive list of all possible hospital procedure codes.

Potential ICD-10-PCS Procedure Codes for Spiration Valve System	
ICD-10-PCS Code	**ICD-10-PCS Description**
Valve Placement	
0BH38GZ	Insertion of Endobronchial Valve into Right Main Bronchus, Via Natural or Artificial Opening Endoscopic
0BH48GZ	Insertion of Endobronchial Valve into Right Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH58GZ	Insertion of Endobronchial Valve into Right Middle Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH68GZ	Insertion of Endobronchial Valve into Right Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH78GZ	Insertion of Endobronchial Valve into Left Main Bronchus, Via Natural or Artificial Opening Endoscopic
0BH88GZ	Insertion of Endobronchial Valve into Left Upper Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
0BH98GZ	Insertion of Endobronchial Valve into Lingula Bronchus, Via Natural or Artificial Opening Endoscopic
0BHB8GZ	Insertion of Endobronchial Valve into Left Lower Lobe Bronchus, Via Natural or Artificial Opening Endoscopic
Valve Removal	
0WPQ8YZ	Removal of Other Device from Respiratory Tract, Via Natural or Artificial Opening Endoscopic

[1]Mahajan AK, Doeing DC, Hogarth DK. Isolation of persistent leaks and placement of intrabronchial valves. J Thorac Cardiovasc Surg 2013;145:626-30.

Spiration™ Valve System for Management of Air Leaks

ICD-10-CM Diagnosis Codes

The Spiration Valve System is indicated for the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy, and Lung Volume Reduction Surgery (LVRS). Hospitals and physicians should check with payers for clinical application of diagnosis codes for payment and coverage. Applicability and usage of these codes may vary per case.

The ICD-10-CM diagnosis codes listed in this table are not intended to be an exhaustive list of all possible diagnosis codes.

Potential ICD-10-CM Diagnosis Codes for Air Leaks	
ICD-10-CM Code	**ICD-10-CM Description**
J93.0	Spontaneous tension pneumothorax
J93.11	Primary spontaneous pneumothorax
J93.12	Secondary spontaneous pneumothorax
J93.81	Chronic pneumothorax
J93.82	Other air leak
J93.83	Other pneumothorax
J93.9	Pneumothorax, unspecified
J95.811	Postprocedural pneumothorax
J95.812	Postprocedural air leak

Medicare Severity Diagnosis Related Groups (MS-DRGs)

The MS-DRG assignment will be influenced by the primary and secondary diagnosis codes reported for the stay along with other procedures that may be performed. Medicare will adjust reimbursement according to case severity which for many MS-DRGs consist of a family of 3 codes pertaining to the level of complication or comorbitities seen during the inpatient stay. The secondary diagnosis codes are used to make the determination of severity.

CMS has designated the EBV insertion procedure codes as affecting assignment to surgical MS-DRGs 163, 164 and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively).[2]

Effective 10/1/19 Medicare inpatient EBV insertion procedure codes will be assigned to one of the three Major Chest Procedure MS-DRGs based on the claim submissions.

Below is the 2022 Medicare national inpatient reimbursement amount for MS-DRGs 163-165.

Medicare Inpatient Hospital Reimbursement		
MS-DRG	**MS-DRG Title**	**Inpatient Allowed Amount**
163	MAJOR CHEST PROCEDURES W MCC	$33,016
164	MAJOR CHEST PROCEDURES W CC	$17,512
165	MAJOR CHEST PROCEDURES W/O CC/MCC	$12,639

Source:
Inpatient Hospital: CMS-1752-F, Table 1A, 1D, and published 2021-8-13 Effective October 1,2021 through 09/30/2022.

Note: Specific crosswalks may vary from the Centers for Medicare & Medicaid Services' General Equivalency Mappings Inpatient payment amounts effective 10/1/2021 through 9/30/2022. MS DRG payment calculated with an average hospital base rate of $6594.31. Base rate of $6594.31 includes the national adjusted operating standardized amounts, labor 67.6% share and 32.4% non-labor share, for hospitals submitting quality and EHR data plus capital adjustment amounts. Represents National Average Medicare Fees (Without Geographic Adjustment) Last Updated December 2021.

[2]Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2021 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting nteroperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals, 84 Fed. Reg. 42144 (November 16, 2020)

Physician and Outpatient Hospital Coding and Reimbursement

CPT® Coding Overview

There are four Category I CPT codes to report bronchoscopy services for insertion and removal of bronchial valve(s) in CPT 2021 Professional Edition. The codes consist of a 2-code series for insertion (initial and each additional lobe), and a 2-code series for removal (initial and each additional lobe).

The Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed within or removed from a single lobe. Physicians should consider all available coding options and select the appropriate CPT code based on the procedure(s) performed.

Below are the coding descriptions for the insertion and removal of bronchial valves.

2022 Medicare Physician and Outpatient Hospital Reimbursement			
CPT® Codes	**CPT® Description**	**Physician Allowed Amount for Hospital/ASC**	**Hospital Outpatient Allowed Amount**
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertionof bronchial valve(s), initial lobe	$209	$5,947*
31651	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertionof bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure[s])	$77	**
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), initial lobe	$200	$3,164*
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with removal of bronchial valve(s), each additional lobe (List separately in addition to code for primary procedure)	$68	$1,528

Represents National Average Medicare Fees Without Geographic Adjustment. Updated January 2022. Rates effective January 1, 2022 through December 31, 2022.

Sources:

- CPT & Description: Copyright 2021 American Medical Association. All rights reserved. Applicable FARS/DFARS apply to government use.
- Medicare Physician Fee Schedule: CMS-1734-F, addendum B published November 19, 2021. Physician payment amounts based on $34.6062 conversion factor effective 01/01/2022 through 12/31/2022. Physician Fee Schedule Procedures and Facility Payments may be subject to Medicare's Multiple Procedure Reduction Rules.
- Hospital Outpatient Fee Schedule: CMS-1751-FC, addendum B released November 2, 2021, effective 01/01/2022 through 12/31/2022.

*J1 code status Outpatient Hospital C-APC procedure is a comprehensive APC limiting payment for other procedures performed that day.

**Payment is packaged into the payment for 31647.

Spiration Valve System Frequently Asked Questions

- **Will payers cover this procedure for prolonged air leak patients?**

  Even though use of the Spiration Valve System requires IRB approval per the Humanitarian Use Device (HUD) guidelines, the Spiration Valve System is FDA-approved as HUD, and therefore can be billed to Medicare Administrative Contractors and commercial payers. Coverage will vary by insurer.

  Absence of a formal coverage policy does not mean the technology or procedure is not covered. In the absence of a formal coverage policy, payers may provide coverage for services that are medically reasonable and necessary on a case-by-case basis. It is always a best practice to contact the insurance companies and determine patient benefits and coverage for a particular new technology or procedure.

  A sample medical necessity letter is included in this guide to assist you in making the case to the payer as to why the procedure was medically necessary for an individual patient.

- **What are the CPT® codes for bronchial valve insertion and/or removal?**

  There are four Category I CPT codes to report bronchoscopy services for the insertion and removal of bronchial valve(s). The codes consist of a 2-code series for insertion procedures (initial and each additional lobe) and a 2-code series for removal procedures (initial and each additional lobe).

  These Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed or removed from a single lobe.

- **Can multiple CPT codes be reported when more than one valve is inserted or removed from a single lobe?**

  No, the Category I CPT codes are intended for billing on a per-lobe basis, including instances when multiple valves are placed within or removed from a single lobe.

- **Can balloon occlusion be billed separately in addition to the valve placement?**

  No, the insertion of bronchial valve CPT codes description includes balloon occlusion as part of the procedure.

- **Are prior authorizations required for the Spiration Valve System?**

  Under Medicare, prior authorizations are not required for any procedure; however, your local Medicare contractor may have specific processes that require submission of materials before a case is performed and billed to your local Medicare contractor.

  Commercial payers vary in their requirements for prior authorization for the Spiration Valve System. The provider should contact the patient's payer prior to performing any procedure that may require prior authorization.

- **Are there Spiration Valve System materials that we can use in our discussions with payers?**

  Please see and review the detailed information in the Supporting Materials Section of this reimbursement guide.

- **Does HCPCS code (or C code) C1889 (implantable/insertable device not otherwise classified) apply to the valve implanted for patients with air leaks?**

  Medicare guidance has determined that a device can be considered implantable if it is for single patient use. Implantable devices are required to remain in the patient post discharge for a period of 30 days. In most cases, the valve will remain in the patient for up to 6 weeks. Depending on the intent of this procedure, the physician may determine, based on their clinical judgment, if the case fits the requirement for classifying this device as an implantable device.

Olympus Reimbursement Resources

OLYMPUS UNITE Reimbursement Helpline Contact Information

Phone: 877-205-1532
Hours: 8:30 am - 5:00 pm Eastern Time
Email: Olympusunite@priahealthcare.com

OLYMPUS UNITE Reimbursement Helpline Services

- Review of the HDE process and payer submission materials.
- Identification of the correct coding for Spiration Valve System.
- Assistance with determining prior authorization polices.
- Review of your local payer's specific coverage and reimbursement criteria.
- Provision of additional details relating to medical documentation.
- Review of payer explanation for denied or underpaid claims.
- Review of coding errors related denials and guidance on how to resubmit or appeal the claim.

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

ATTACHMENT A: FDA HDE Approval Letter

ATTACHMENT B: Requesting Prior Authorization

ATTACHMENT C: Sample Letter of Medical Necessity

ATTACHMENT D: Instructions For Use – Spiration Valve System

ATTACHMENT E: Instructions For Use – Airway Sizing Kit

ATTACHMENT F: Spiration Valve System Procedure Overview

Supporting Documentation

A: FDA HDE Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 17, 2015

Cyndy Adams
Senior Regulatory Affairs Manager
Spiration, Inc.
6675 185th Avenue N.E.
Redmond, WA 98052

Re: H060002 S007
Spiration Valve System
Filed: February 6, 2015
Amended: June 4, 2015

Dear Ms. Adams:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your humanitarian device exemption application (HDE) supplement, which requested approval for a modified version of the reloadable catheter and to introduce a 9mm valve. The device, as modified, will be marketed under the trade name Spiration Valve System and is indicated for control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or lung volume reduction surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Spiration Valve System use is limited to 6 weeks per prolonged air leak. Based upon the information submitted, the HDE supplement is approved subject to the conditions described in the approval order for your original HDE. You may begin commercial distribution of the device as modified by your HDE supplement upon receipt of this letter.

The sale, distribution, and use of this device are limited to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) under the authority of section 515(d)(1)(B)(ii) of the FD&C Act. In addition, in order to ensure the safe use of the device, FDA has further restricted the device within the meaning of section 520(e) of the FD&C Act under the authority of section 515(d)(1)(B)(ii) of the FD&C Act insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the FD&C Act.

Continued approval of this HDE is contingent upon the submission of periodic reports, required

Supporting Documentation

A: FDA HDE Approval Letter (Continued)

Page 2 – Ms. Adams

under 21 CFR 814.126, at intervals of one year (unless otherwise specified) from the date of approval of the original HDE. Two copies of this report, identified as "Annual Report" and bearing the applicable HDE reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.126.

In addition to the above, an HDE holder is required to maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing institutional review boards (IRBs), as well as any other information requested by a reviewing IRB or FDA.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Before making any change affecting the safety or effectiveness of the device, you must submit an HDE supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39 except a request for a new indication for use of for a humanitarian use device (HUD). A request for a new indication for use for an HUD shall comply with the requirements set forth in 21 CFR 814.110 which includes obtaining a new designation of HUD status for the new indication for use and submission of an original HDE application in accordance with §814.104. The application for the new indication for use may incorporate by reference any information or data previously submitted to the agency.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to:

Supporting Documentation

A: FDA HDE Approval Letter (Continued)

Page 3 – Ms. Adams

(1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of an HDE. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that as soon as possible and before commercial distribution of your device you must submit an amendment to this HDE with copies of all approved labeling in final form. The labeling will not routinely be reviewed by FDA staff when HDE supplement applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above HDE number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
HDE Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have questions concerning this approval order, please contact James Lee Ph.D. at (301) 796-8463.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

B: Requesting Prior Authorization

Prior authorization is a process that varies among different payers. It is always best to contact your payer representative to obtain a thorough understanding of the steps involved in making a prior authorization request. Here are some common requirements in obtaining prior authorization. The key in all coding and billing to payers is to be truthful and not misleading and make full disclosures to the payer about how the product has been used and the procedures necessary to deploy and remove the product when seeking reimbursement for any product or procedure.

Documentation

Identify the documentation that the payer requires in order to review the prior authorization request. Generally, a letter of medical necessity is needed. This document summarizes the rationale for the payer to provide coverage for the therapy in question.

Request Routing

Ensure that you understand who will review your request and how to route your request to the payer's review staff. Some departments provide specific routing instructions and have a preference for fax, email or written correspondence. Requests are easily misplaced. Please follow-up with review staff to ensure your request has been received and periodically thereafter to ensure the request is being addressed.

Timelines

When speaking to the payer representative, clarify the timeframe in which original documentation and supplemental documents must be provided and how long it will take to receive an answer. Requests may be rejected if the applicant is not diligent in responding to requests for additional information.

Denials

Determine your avenues for payer appeal if the prior authorization is denied. Most payers have multiple levels of appeal that allow for review by different internal bodies. An initial denial can be subsequently overturned on appeal.

Recertification

When a prior authorization request has been approved, be aware that some decisions may have a limited timeframe for which the approval is effective. In some cases, recertification may be necessary if the initial timeframe is exceeded.

Supporting Documentation

C: Sample Letter Of Medical Necessity

NOTE: The text below is only a guide and should not be replicated verbatim. Customize to individual patient and clinical opinions/justification.

[DATE]
[prior authorization fax number or mailing address]
Patient Name: [Patient Name}
Member ID#: [Member ID]
Date of Birth:

Date of Service : [MM/DD/YYYY]
Place of Service: [Facility/Hospital Name], [Street address], [City], [State], [Zip]
Performing physician: [Physician Name], [NPI]

CPT Codes: [Insert CPT Codes]
ICD-9- Procedure code: [Insert ICD-9 Procedure codes]
Diagnosis codes: [Insert diagnosis codes]

Prior Authorization for coverage for the assessment, insertion and removal of the Spiration Valve System

Dear [RECIPIENT],

I am writing to request a prior approval for coverage of the Spiration Valve System for treatment of a postoperative air leak. [Patient Name] has been diagnosed with [insert specific air leak diagnosis code description] on postoperative day [insert day]. The patient's current status is [insert detail of impairment and how it impacts quality of life, caregiver employment, etc].

It is my expert medical opinion that a prolonged hospital stay is not in the best interest of this patient's health and the placement of the Spiration Valve System will speed recovery and discharge from the hospital. The Spiration valves are delivered via a minimally invasive procedure that has shown to reduce or stop air leaks by limiting airflow to the damaged tissue. Given the condition of my patient I do not believe any other option will resolve their current medical issue.

A landmark study published in the European Respiration Journal demonstrated the use of the Spiration Valve as a safe and effective treatment for patients suffering from prolonged air leaks after anatomic resection of the lung.[1] After placement of the Spiration Valves, patients in the study experienced air leak cessation at a median of two days and chest tube removal at a median of four days. During the entire study there were no deaths, cardiovascular complications, or implant-related events such as infection distal to valve, lobar atelectasis, hemoptysis, pneumothorax or expectoration.[1]

The Spiration Valve System has been available in the United States under Humanitarian Device Exemption since October 2008.

Based on the above information and my medical judgment, I recommend the use of the Spiration Valve in this patient for the control of his/her prolonged air leak and improvement in their clinical course.

Supporting Documentation

C: Sample Letter Of Medical Necessity (Continued)

NOTE: The text below is only a guide and should not be replicated verbatim. Customize to individual patient and clinical opinions/justification.

We are requesting confirmation that this treatment be considered a covered benefit based on medical necessity and that associated professional fees for the procedure and follow-up will be covered. I ask that you concur with this rationale and consider the [PROCEDURE] using the Spiration Valve System and its associated materials and services to be a covered benefit for [PATIENT'S NAME].

I am enclosing a summary of procedures and dates of service that [PATIENT'S NAME] has already undergone and a bibliography of clinical literature supporting the use of the Spiration Valve System. [Note if relevant: prior treatments and outcomes, additional information on the patient's history and implications of prolongation of the air leak. A timeline is useful.]

I would like to sincerely thank you for taking the time to review this information and for considering coverage. If you have any questions, please feel free to contact me so that I can be of further assistance.

Sincerely,
[SIGNATURE]

[1]Dooms C, Decaluwe H, Yserbyt J, et al. Bronchial valve treatment for pulmonary air leak after anatomic lung resection for cancer. Eur Respir J 2014;43(4):1142-8.

Caution

The Spiration Valve System is indicated to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). An air leak present on postoperative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Spiration Valve System use is limited to 6 weeks per prolonged air leak. The effectiveness of this device for this use has not been demonstrated.

Humanitarian Device. Authorized by Federal Law for use in the control of prolonged air leaks of the lung or significant air leaks that are likely to become prolonged following lobectomy, segmentectomy or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician.

Contraindications

Patient is unable to tolerate a flexible bronchoscopy procedure. Allergy to latex and nickel.

Warnings

Atelectasis may occur after the air leak seals and patients should be monitored for this possible complication.

General Precautions

The Spiration Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis. Only use a bronchoscope with a working channel of 2.6mm or larger. Do not use the Spiration Valve System for other than its intended use. Potential Adverse Effects: Atelectasis; Death; Infection in the tissue distal to a valve; Local airway swelling or edema at site of valve implantation; Pneumothorax.

For full prescribing information go to: svs.olympusamerica.com

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

D: Instructions For Use – Spiration Valve System

Spiration®

SPIRATION VALVE SYSTEM

INSTRUCTIONS FOR USE

Humanitarian Device for Use in the Control of Air Leaks

STERILE EO Sterilized by EO. Sterile unless package opened or damaged. | Do Not Resterilize | Do Not Re-Use | See Instructions For Use | Temperature Limits: -15°C to +50°C

CAUTION: Humanitarian Device. Authorized by Federal law for use in the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal Law restricts this device to sale by or on the order of a physician.

The Spiration® Valve System is protected by one or more of the following U.S. patents: 6,293,951, 6,258,100, 7,757,692, 7,875,048, 7,434,578, 7,842,061, 7,887,585, 8,136,230, 8,043,301, 7,887,585 and other patents pending.

Gyrus ACMI, Inc.

6675 – 185th Avenue NE, Redmond, WA 98052 USA

1. Intended Use

The Spiration Valve System is a device to control prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). An air leak present on post-operative day 7 is considered prolonged unless present only during forced exhalation or cough. An air leak present on day 5 should be considered for treatment if it is: 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise. Spiration Valve System use is limited to 6 weeks per prolonged air leak.

2. Spiration Valve System Description

The Spiration Valve System consists of a Spiration Valve (IBV) in Cartridge ("Spiration Valve" or "valve") and a Deployment Catheter ("catheter") and Loader ("loader"). The Airway Sizing Kit is an accessory to the Spiration Valve System used to determine the appropriate valve size for each target airway (see Instructions for Use, Airway Sizing Kit).

2.1 Spiration Valve in Cartridge

The valve is designed to limit airflow to the portions of the lungs distal to the valve, while still allowing mucus and air movement in the proximal direction. The valve is comprised of a Nitinol frame and a polymer membrane. The membrane is held against the airway mucosa by 6 flexible struts and will expand and contract with airway movement during breathing. The 5 anchors have tips that gently secure the valve to the airway wall at a controlled depth, preventing the valve from migrating. The valve is designed to be removed by grasping the removal rod with flexible bronchoscopy forceps.

The valve is available in 5, 6, 7, and 9 mm diameters and is pre-packaged in a disposable cartridge that protects the valve during storage and fits in the loader (see Figure 1). The cartridges are uniquely marked to distinguish one valve size from the other. The appropriate valve size is selected after an air leak(s) has been isolated and the airways have been sized using the Airway Sizing Kit.

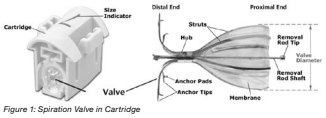


Figure 1: Spiration Valve in Cartridge

2.2 Deployment Catheter and Loader

The loader is a tool used to insert the valve into the tip of the catheter. After the cartridge is placed in the loader, the catheter tip is inserted into the loader and the loader plunger is depressed to load the valve into the tip of the catheter (see Figure 2). The catheter is used to deliver the valve to its target location. The loader and catheter are designed to load and deploy up to a maximum of 10 valves during a single patient procedure. If there are more than 10 valve deployments, a new catheter must be opened and used.

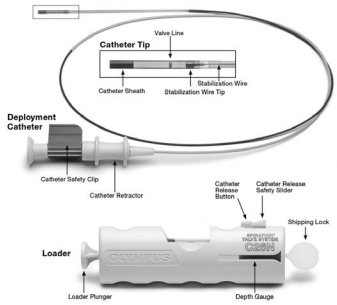


Figure 2: The Deployment Catheter and Loader

The catheter can be passed through a flexible bronchoscope with an instrument channel inner diameter of 2.6mm or larger. After loading, the catheter is advanced through the bronchoscope instrument channel to the target location. The distal end of the catheter includes a valve line which marks the target position of the proximal end of the valve when deployed. The valve is deployed when the operator actuates the deployment handle of the catheter, retracting the catheter sheath to release the valve.

2.3 Resolution of Air Leaks

Treatment of an air leak with a valve may not require complete blockage of all air leakage. Even if not completely sealed, a substantial reduction in an air leak using valves may accelerate the resolution of an air leak, as the progression through the clinical stages of the air leak is improved. For example, if a continuous air leak is not completely resolved, but changed to an expiratory or forced exhalation pattern after valve treatment, such a change will allow the physician to consider discharging the patient with the chest tube(s) connected to a Heimlich valve.

3. Contraindications

- Patient is unable to tolerate a flexible bronchoscopy procedure.
- Patient is allergic to latex.
- Patients with known or suspected sensitivity or allergy to nickel.

4. Warnings

- Atelectasis may occur after the air leak seals; patients should be monitored for this possible complication.

5. Precautions

5.1 General Precautions

- Use of the catheter requires bronchoscopy technical skills and adequate training. The operator must be a physician or medical personnel under the supervision of a physician and be trained in clinical bronchoscopy techniques and the use of the Spiration Valve System. The following instructions will give technical guidelines but do not obviate formal training in bronchoscopic procedures.
- The Spiration Valve System should not be used for patients who have active asthma, bronchitis or clinically significant bronchiectasis.
- Only use a bronchoscope with an instrument channel inner diameter of 2.6mm or larger.
- Valve placement should be done only after air leak isolation and airway sizing with the calibrated balloon catheter.
- Valve placement and removal must be done under bronchoscopic observation with visualization of the target airway.
- Do not allow lubricants to contact the catheter, loader, or valve.
- Once a valve has been loaded and/or deployed, do not attempt to reuse or re-deploy the valve.
- The valve is not designed to be repositioned after it is deployed from the catheter. If the position of the deployed valve is not optimal or appropriate; the valve should be removed and discarded.
- Do not remove the valve from the cartridge.
- Do not use the Spiration Valve System for other than its intended use.
- Do not reuse the catheter and loader for more than one patient procedure. The catheter and loader are not designed to be recleaned, reprocessed, or resterilized.
- Do not deploy more than 10 valves using the catheter and loader. If more than 10 valve deployments are needed, a new catheter and loader must be opened and used.

5.2 MRI Information

The Spiration Valve was determined to be MR-Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Non-clinical testing has demonstrated that the Spiration Valve is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:
- Static magnetic field of 3-Tesla or less
- Spatial magnetic gradient field of 720-Gauss/cm or less
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning.

In non-clinical testing, the Spiration Valve produced a temperature rise of less than or equal to 0.5° C at a maximum MR system reported whole-body-average specific absorption rate (SAR) of 3-W/kg for 15 minutes of MR scanning in a 3-Tesla MR system (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI).

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the Spiration Valve. Optimization of MR imaging parameters is recommended.

6. Potential Adverse Effects

- Atelectasis
- Bleeding observed from an airway treated with a valve
- Bleeding due to valve removal and complications of such bleeding such as airway obstruction by blood clot
- Bronchitis
- Damage in the airway and/or tissue near a valve
- Death
- Infection in the tissue distal to a valve
- Local airway swelling or edema at site of valve placement
- Migration of valve out of the lung or within the lung
- Persistent cough
- Pneumothorax
- Shortness of breath
- Tissue hyperplasia or other reaction at site of valve placement
- Valve fracture

7. Preparation for the Procedure

7.1 Items Required and Recommended for Spiration Valve Procedure

Items required (provided with the Spiration Valve System):
- Spiration Valve in Cartridge (multiple sizes)
- Deployment Catheter and Loader (one per patient)
- Airway Sizing Kit
- Olympus Balloon Catheter B5-2C

Additional ancillary equipment required (not provided with the Spiration Valve System):
- Flexible bronchoscope with an instrument channel inner diameter of 2.6mm or larger

Additional ancillary equipment recommended (not provided with the Spiration Valve System):
- An endotracheal (ET) tube of 8.5 or larger should be considered for better control of the upper airways and improved ventilation during isolation of the air leak(s)
- Olympus balloon catheter B7-2Q or a balloon catheter that inflates to 13mm or larger (for balloon occlusion only)

7.2 Items Recommended for Spiration Valve Removal Procedure

- Bronchoscopy forceps
- Flexible bronchoscope compatible with forceps
- An endotracheal (ET) tube (see section 11.1 for details)

8. Packaging Inspection, Storage, and Handling

8.1 Checking the Package

The catheter and loader are supplied sterile and packaged in a sealed pouch. The valve is also supplied sterile and is packaged in a sealed pouch separate from the catheter and loader. Prior to use, inspect the pouches and verify that the seals are intact and that there are no holes or tears.

Caution: If sterility or performance of the device is suspected to be compromised, do not use the device; contact your local Olympus representative.

8.2 Storage Conditions

Store the product at room temperature in a clean and dry environment. Do not use the valve in the cartridge or the catheter and loader if it has been exposed to temperatures above 50° C or below -15° C.

8.3 Handling

- The Spiration Valve System is supplied sterile. Do not attempt to re-sterilize the Spiration Valve System components.
- Do not reuse the catheter and loader for more than one patient procedure.
- Do not reuse a valve once it has been deployed.
- Do not remove the valve from the cartridge.

9. Clinical Use of the Spiration Valve

9.1 Spiration Valve Deployment

- Using bronchoscopic techniques, and only after evaluation and sizing of airways, valves should be deployed in selected airways.
- The location for the deployment of valves may be determined by selective airway occlusion using a balloon catheter.
- Treatment of an air leak may require deployment of a valve in one or more airways. Valves may be deployed in any segment or sub-segment of the lung anatomy (including the lingular segments) that communicates with and contributes to the persistence of an air leak. Single or multiple airway segments of the lungs may be treated with valves. Treatment should be limited to no more than 3 segments by placing valves in segmental or sub-segmental bronchi in the target lung to avoid excessive isolation of tissue from ventilation.

9.2 Spiration Valve Removal

All valves placed for air leaks will be removed using bronchoscopic techniques and bronchoscopy forceps to grasp the removal rod tip.

Conditions and criteria for valve removal:
- Air leak has resolved and damaged tissue is considered sealed.
- Six (6) weeks or less after valve placement.
- Before further intervention to resolve an air leak, such as surgical repair or pleurodesis.

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

D: Instructions For Use – Spiration Valve System (Continued)

10. Operator's Instructions

10.1 Isolating the Air Leak by Balloon Occlusion

Observation of air bubbles passing through the water seal system connected to the chest tube(s) is a tool for measuring air leaks (it shows presence, size, and changes).

1. Insert the balloon catheter into the instrument channel of the bronchoscope. Refer to the Instruction for Use provided with the balloon catheter for its operation. Start in proximal airways before moving distally, as needed.
2. Evaluate if an airway segment contributes to the air leak by slowly inflating the balloon until the balloon seals the airway. Then, determine if the air leak has decreased or stopped.
3. If the air leak has not decreased or stopped, deflate the balloon, pull the balloon catheter into the bronchoscope, and evaluate the next airway segment.
4. If the air leak decreases or stops, this indicates the airway contributes to the air leak. Follow airway sizing instructions for appropriate valve placement.
5. Multiple airways may contribute to an air leak. Additional balloon occlusions and valve placements may be required.

10.2 Selecting the Spiration Valve Size

Use a balloon catheter (B5-2C) together with the Airway Sizing Kit to determine the appropriate valve size to use for each target airway.

Caution: Incorrect valve size will reduce device effectiveness.

10.3 Loading the Spiration Valve

1. Remove the loader and catheter from the packaging.
2. Release the disposable shipping lock from the loader by pushing the catheter release safety slider forward, then pressing the catheter release button down until an audible "click" is heard. Remove the shipping lock from the loader.

   Caution: If a "click" is not heard, fully re-insert the shipping lock into the loader. Repeat step 2.
3. Pull the loader plunger all the way back.
4. Remove the catheter from the protective tube in the packaging.
5. Select a cartridge of the determined valve size. Remove the cartridge from the packaging. Verify a valve is inside the cartridge (see Figure 3).

Figure 3: Spiration Valve and Cartridge

6. Insert the cartridge into the loader until it locks into place.
7. Verify the catheter retractor is fully forward and the green safety clip is installed over the yellow portion of the handle.
8. Inspect the catheter's distal tip for damage prior to inserting it into the loader. Damage may include kinks, deformation, tears, or protrusions. If the catheter is damaged, use a new catheter.
9. Grasp the catheter as shown in Figure 4 so that it can be fully inserted into the loader without kinking or damage. There is a depth gauge (see Figure 4) on the side of the loader that shows where the catheter should be grasped while inserting it into the loader.

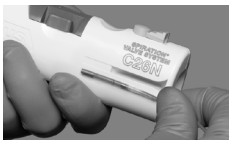


Figure 4: Depth gauge on loader used to determine where to grasp Deployment Catheter

10. Insert the catheter into the loader until an audible "click" is heard.

    Caution: If a "click" is not heard, release the catheter by pushing the catheter release safety slider forward, then pressing the catheter release button down until an audible "click" is heard. Remove the catheter from the loader. Repeat step 8. Not hearing a "click" when inserting the catheter into the loader means the catheter has not been properly locked into place inside the loader and the valve may not load properly.
11. Fully push the loader plunger to load the valve into the catheter.
    Verify that the plunger cannot be pushed any further.
12. Release the catheter by pushing the catheter release safety slider forward, then pressing the catheter release button down until an audible "click" is heard. Remove the catheter from the loader.
13. **Visually inspect** the catheter tip to ensure that the valve is loaded correctly.

    Caution: If any anchor tips protrude from the catheter tip, do not insert the catheter into the bronchoscope. In this case, the valve must be replaced. Pull the catheter retractor to eject the valve for disposal. Direct the catheter tip into a container to avoid losing the ejected valve. Obtain a new cartridge and load the new valve into the catheter by repeating previous steps.
14. Pull the loader plunger all the way back and remove the cartridge.

10.4 Deployment of the Spiration Valve

1. While holding the catheter at the proximal end of the catheter tip, carefully insert the catheter into the instrument channel of the bronchoscope using slow, short strokes.

   Important:
   - Only use a bronchoscope with an instrument channel inner diameter of 2.6 mm or larger.
   - Do not bend or force the distal end of the catheter while inserting into the bronchoscope. This may cause a kink in the catheter which may prevent the valve from deploying.
2. While the bronchoscope is in a central airway without a bend, advance the catheter until the stabilization wire tip and removal rod tip are visible.

   Caution: Applying excessive force to advance the catheter through a bend in the bronchoscope could result in damage to the catheter and/or the instrument channel of the bronchoscope.

Preparing to Advance the Catheter to the Target Location

3. Retract the catheter into the bronchoscope until the end of the catheter tip is just visible at the end of the bronchoscope and does not interfere with its operation.

Positioning the Bronchoscope for Spiration Valve Deployment

4. **Under bronchoscopic observation**, advance and position the bronchoscope so that the target airway location is visible and the tip of the catheter can be directed into the target airway site without bending or kinking the catheter.
5. Advance the catheter so that the valve line passes beyond the target location.

   Caution:
   - While directing the catheter to the target airway site, do not apply excessive force to advance the catheter.
   - If it is necessary to remove the loaded catheter from the bronchoscope, relax the bronchoscope's distal tip first.
6. Pull the catheter back slowly so that the valve line is at the target location. The valve line marks the position where the proximal end of the valve will contact the airway wall once deployed. After deployment, the valve may settle 1–2mm distally over time, so the operator should account for this effect.

   Caution: If the catheter is pushed to position prior to deployment, the valve may deploy distal to the target location.
7. If the valve line is not at the desired target location, repeat steps 5 and 6. Performing steps 5 and 6 in sequence reduces movement of the catheter inside the bronchoscope channel during deployment.

Deploying the Spiration Valve

Important:
- The valve line and target location must be visible prior to deploying the valve.
- Hold the catheter sheath at the bronchoscope instrument channel entry port to maintain the valve line at the target location, so the catheter does not move during deployment.

8. **Under bronchoscopic observation**, using a smooth continuous motion, pull on the catheter retractor to deploy the valve. Forces on the catheter can be decreased by limiting bends in the bronchoscope and the catheter and/or by reducing the speed that the catheter retractor is pulled during deployment.
9. Once the valve is completely deployed, immediately remove the catheter from the bronchoscope.
10. While holding the catheter uncoiled, advance the catheter retractor and re-install the safety clip.

Checking Spiration Valve Placement

11. Visually examine the valve for position and fit. The valve should be opened and opposing against all borders of the airway.

    Caution: If the position of the deployed valve is not optimal or appropriate, remove and properly dispose of the valve.
12. After valve deployment, evaluate the reduction of the air leak and determine if additional valves should be deployed.
13. As needed, repeat the loading and deployment steps for each additional valve required.

    Caution: The catheter and loader are designed to load and deploy up to 10 valves. After 10 valves are loaded and deployed from a loader and catheter, use a new catheter and loader. Using a catheter and loader more than 10 times may lead to system failure.

    Important: Ensure the catheter safety clip is installed onto the catheter first before loading the next valve.

11. Spiration Valve Removal

11.1 Recommended Use of ET Tube

Removal of valves should be conducted **under bronchoscopic observation**. It is recommended that valves should be removed through an endotracheal (ET) tube or other intubation system that facilitates access to the airways for the following reasons:
- Allows better control of the upper airways and facilitates ventilation and anesthesia
- Facilitates the manipulation of the flexible bronchoscope into the areas where valves need to be removed
- Facilitates removal of the valves by protecting the vocal cords and other structures of the upper airways

The procedure can be performed without intubation, but this decision should be made by the physician after he or she has acquired enough experience with the Spiration Valve System.

11.2 Removing the Spiration Valve

1. Insert the appropriate forceps (see Table 1) through the instrument channel of the bronchoscope, directing the forceps to the target location (see Instructions for Use provided by the forceps manufacturer).

Table 1: Forceps Selection

Forceps	Recommended Use
Cupped Biopsy	When the removal rod tip can be visualized and accessed by the biopsy forceps.
Rat-Tooth Jaw Grasping	When the removal rod shaft is being grasped.
Pediatric Biopsy	When the maneuverability of the bronchoscope is limited by standard sized forceps but the removal rod tip can be visualized and grasped.

2. Grasp the removal rod shaft or removal rod tip with the appropriate forceps and gently pull the valve until it is dislodged from the airway wall. Use care to make sure that the removal rod does not get caught in the fenestration of the forceps when removing the valve (see Figure 5).

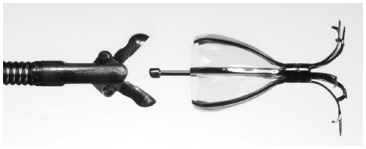


Figure 5: Spiration Valve Removal with Forceps

Important: Before removing the valve from the trachea, pull the valve close to the end of the bronchoscope (see Figure 6).

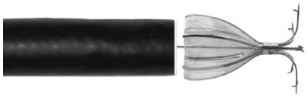


Figure 6: Spiration Valve close to the end of the bronchoscope prior to removal

3. While still firmly holding onto the valve with the forceps, simultaneously remove the bronchoscope and the forceps from the patient.

   Caution: Do not attempt to bring the whole valve through the instrument channel of the bronchoscope. This may cause damage to the bronchoscope.
   Important: Do not release the valve from the forceps until the valve is completely removed from the patient. During removal, the valve struts may invert.
4. All valves are single use only.

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

D: Instructions For Use – Spiration Valve System (Continued)

12. Clinical Studies

12.1 Post Approval Study

A post approval study of the Spiration Valve System was conducted. The study methods and results are summarized in Table 3.

Table 3: Post Approval Study Methods and Results

Study Methods	
Objective	Characterize the safety profile of the Spiration Valve System
Design	Prospective Multi-Center Observational Study
Study Population	Inclusion Criteria • Subject has an air leak present on day 7 after lobectomy, segmentectomy, or lung volume reduction surgery (LVRS), or on day 5 if the air leak is 1) continuous, 2) present during normal inhalation phase of inspiration, or 3) present upon normal expiration and accompanied by subcutaneous emphysema or respiratory compromise Exclusion Criteria • Air leak only on force exhalation or cough • Subject has significant active asthma, pneumonia, bacterial bronchitis or clinically significant bronchiectasis • Subject is unable to provide informed consent and there is no designated authority to sign for the incapacitated patient • Subject is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures Subject has co-morbidities or factors that will prevent follow-up during the study period
Data Source	Study specific case report forms
Key Study Endpoints	• Adverse events reported during the study were analyzed and summarized. • Probable benefit information gathered during study was analyzed and summarized.
Number of Study Sites, Subjects, and Follow-up Rate	39 subjects were enrolled at 11 sites 100% (32/32 as per protocol)
Study Visits and Length of Follow-up	Following valve placement, subjects were followed through valve removal or 6 weeks, whichever was earlier
Results	
Final Safety Findings	Two adverse events were reported for the 32 subjects treated. • 1 systolic arrest occurred prior to valve placement; not device related • 1 atelectasis and thick mucus secretion; possibly device related
Final Effectiveness Findings	• Of the 39 subjects enrolled, 32 received valves (as per protocol); 7 subjects did not receive valves due to inability to localize air leak (5), resolution of air leak (1), and inability to access air leak.30 (94%) showed a positive response to valve placement. Two (6%) showed no improvement in air leak. • 30 (94%) showed a positive response to valve placement. Two (6%) showed no improvement in air leak. • 11 of 30 responders completely resolved, 19 showed improvement. • Post-Procedure Days in Hospital: 6.0±6.1 (0 min, 27 max); 0.7±2.2 in ICU (0 min, 10 max) • Days Valves in Place (n=27): 53.6±33.1 (10 min; 185 max)
Study Strengths / Weaknesses	Strengths • Prospective recruitment • Thorough follow-up for adverse event determination Weaknesses • Lack of control arm to determine underlying adverse event rate in population • Lack of discrete secondary endpoints to evaluate efficacy • Limited number of female patients (10), small sample size (32)

13. Patient Information

A Patient Information Pamphlet is available for potential patients (Patient Information for the Spiration Valve System, Humanitarian Device for Use in the Control of Air Leaks). Patients who receive treatment will be given a wallet card that indicates the patient has valve(s) and lists the procedure doctor's contact information.

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

E: Instructions For Use – Airway Sizing Kit

Spiration®

AIRWAY SIZING KIT

INSTRUCTIONS FOR USE

Humanitarian Device for Use in the Control of Air Leaks

STERILE EO — Sterilized by EO. Sterile unless package opened or damaged.
Do Not Resterilize
Do Not Re-Use
See Instructions For Use
Temperature Limits: -15°C to +50°C

CAUTION: Humanitarian Device. Authorized by Federal law for use in the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal Law restricts this device to sale by or on the order of a physician.

The Spiration® Valve System is protected by one or more of the following U.S. patents: 7,476,203, 7,887,585 and other patents pending.

Gyrus ACMI, Inc.
6675 – 185th Avenue NE, Redmond, WA 98052 USA

1. Intended Use

The Airway Sizing Kit is an accessory to the Spiration Valve System used to determine the appropriate valve size to use for each target airway. A balloon catheter is used first in conjunction with the Airway Sizing Kit to determine, by selective airway occlusion, the location for the placement of valves to control prolonged air leaks.

2. Device Description

The Airway Sizing Kit consists of a glass syringe with a plunger and a calibration gauge (see Figure 1). The glass syringe has a volumetric scale (in microliters, µL) that is used with a balloon catheter and the calibration gauge to establish a valve size reference. To ensure the appropriate valve size is selected for each targeted airway, the balloon catheter must be calibrated prior to its use as a sizing tool. One balloon catheter is used to measure all of the airways to be treated for a single patient.

A compliant balloon is acceptable to use for airway sizing: the Olympus® B5-2C balloon. The balloon is filled with saline and calibrated with the calibration gauge. During the sizing process, the calibrated balloon is inflated at the target airway location. The saline volume used to inflate the balloon indicates the appropriate valve size to use at the target location.

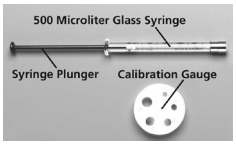


Figure 1: Airway Sizing Kit

3. Contraindications

- Do not use this Airway Sizing Kit for other than its intended use.
- Patient is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures.
- See contraindications for the Spiration Valve System.
- Patient is allergic to latex.

4. Precautions

- Use of the Airway Sizing Kit requires bronchoscopy technical skills. The operator must be a physician or medical person under the supervision of a physician and be trained in clinical bronchoscopy techniques. The following instructions will give technical guidelines but do not obviate formal training in the use of this device.
- The Olympus balloon catheters contain natural latex rubber, which may cause allergic reactions. Do not use this product on a latex-sensitive patient.
- Only use the recommended balloon catheters with the Airway Sizing Kit.

5. Potential Adverse Effects

- Adverse effects associated with flexible bronchoscopy.
- Allergic reaction to latex specific to latex balloon use.

6. Items Required and Recommended for Use with the Airway Sizing Kit

Items required (provided with the Airway Sizing Kit):
- Calibration gauge
- 500µl glass syringe
- Syringe plunger
- Airway Sizing Worksheet
- Olympus balloon catheter B5-2C

Additional ancillary equipment required (not provided with the Airway Sizing Kit):
- Standard 10cc sterile syringe with Luer lock fitting
- Sterile saline

Additional ancillary equipment recommended (not provided with the Airway Sizing Kit):
- Olympus balloon catheter B7-2Q or a balloon catheter that inflates to 13mm or larger (for balloon occlusion only).

7. Packaging Inspection, Storage, and Handling

- The Airway Sizing Kit is packaged sterile in a sealed tray. Do not attempt to resterilize the Airway Sizing Kit. Contact your local Olympus representative if the integrity of the packaging has been compromised.
- Do not use the Airway Sizing Kit if it has been exposed to temperatures above 50° C or below -15° C.
- Do not use the Airway Sizing Kit for more than one patient procedure.
- The Airway Sizing Kit is not designed to be recleaned, reprocessed or resterilized.

8. Preparation of the Balloon Catheter for Sizing

Please familiarize yourself with the Instructions for Use provided by the balloon manufacturer. Note: The Olympus balloon catheter contains natural latex rubber, which may cause allergic reactions. Do not use this product on a latex-sensitive patient.

8.1 Preparing the Balloon Catheter

1) Remove the balloon catheter and Airway Sizing Kit components from the packaging. Place the items on a clean or sterile field.
2) Remove the black lightproof cap from the balloon (see Figure 2).

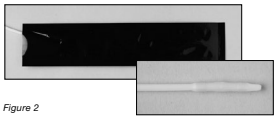


Figure 2

NOTE Do not discard the lightproof cap. This will be used later in the procedure.

3) Confirm that the stopcock supplied with the system is firmly attached (see Figure 3).

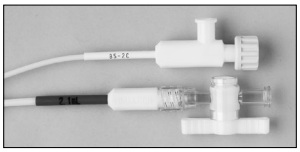


Figure 3

NOTE Do not over-tighten the stopcock, as it is possible to damage the luer fittings.

4) Fill the 10cc syringe with approximately 3cc of sterile saline.
5) Purge any air from the 10cc syringe.
6) Connect the 10cc syringe to the stopcock port.
7) With the 10cc syringe oriented vertically, pull the syringe plunger to approximately the 10cc mark and hold for at least 10 seconds to create a vacuum removing the air from the balloon (see Figure 4).

Figure 4

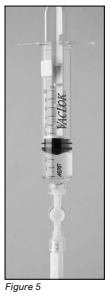


Figure 5

8) While maintaining vacuum, tap on the side of the syringe to assist in freeing bubbles from the stopcock.
9) Keeping the 10cc syringe vertical, slowly release the plunger on the 10cc syringe until the system is no longer under vacuum (see Figure 5).

NOTE Visually confirm that the balloon is fully deflated after this step.

10) Set aside the balloon with the 10cc syringe still attached.
11) Using sterile saline, wet the plunger for the glass syringe from the Airway Sizing Kit and completely insert it into the 500 microliter (µL) glass syringe.
12) Fill the glass syringe with at least 500 µL of sterile saline (see Figure 6).

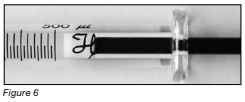


Figure 6

13) Remove any air bubbles from the syringe (see Figure 7).

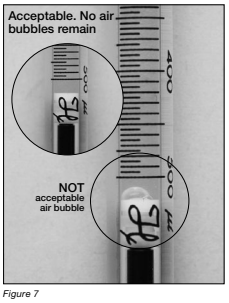


Figure 7

Spiration™ Valve System for Management of Air Leaks

Supporting Documentation

E: Instructions For Use – Airway Sizing Kit (Continued)

14) Set the 500µL syringe to the 480µL mark (see Figure 8).

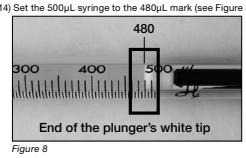


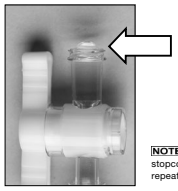
Figure 8

NOTE Holding the glass syringe against a dark background may assist in reading the syringe volume. Always read the volume at the end of the white tip of the plunger.

15) Set aside the glass syringe.

16) Remove the 10cc syringe from the balloon stopcock.

17) Fill the void space in the stopcock with saline from the 10cc syringe until it is full (see Figure 9).



NOTE Ensure no large bubbles are trapped in the stopcock connector. If necessary, steps 6-9 may be repeated.

Figure 9

18) Attach the glass syringe to the stopcock port on the balloon.

NOTE Do not overtighten the syringe as it is possible to damage the luer fittings.

19) Exercise the balloon once by fully inflating and deflating it: inject the entire contents of the syringe into the balloon and then slowly draw back the glass syringe plunger to baseline the syringe at 500µL (see Figure 10). Ensure the balloon is fully deflated.

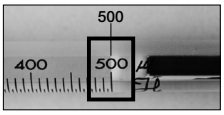


Figure 10

8.2 Calibrating the Balloon

A worksheet is included to record the calibration data for:

- Balloon Calibration
- Airway Sizing

Figure 11

1) Wet the balloon and calibration gauge with sterile saline.
2) Place the deflated balloon in the center of the "E" sizing gauge hole on the calibration gauge. Slowly inflate the balloon until it just touches all sides of the "E" gauge hole and the balloon drags slightly when moved in and out of the gauge hole. (see Figure 11).
3) Read the volume at the white end of the syringe plunger.
4) Obtain the Airway Sizing Worksheet, and record the glass syringe volume next to the "E" on the Valve Selection Guide and on the Balloon Calibration sections.
5) Deflate the balloon by returning the plunger to the 500uL mark.
6) Repeat steps 2 through 5 for the remaining sizing gauge holes ("A", "B", "CAL", and "D").
7) Connect each of the points on the Balloon Calibration section with a straight line. Verify that the curve is continuous (see Figure 12).
8) Fully deflate the balloon by returning the plunger to the 500uL mark. Cover the balloon with the lightproof cap and place it in a safe, clean area until ready to use in the airway.

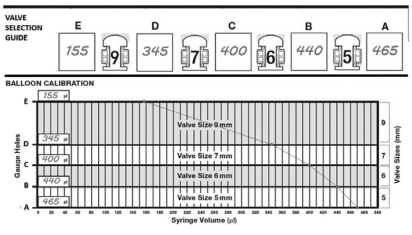


Figure 12

8.3 Selecting the Valve Size

1) Insert the deflated balloon into the instrument channel of the bronchoscope. Keep the tip of the balloon catheter just inside of the distal end of the bronchoscope.
2) Maneuver the bronchoscope to the airway location. Advance the balloon into the target airway.
3) Align the middle of the balloon with the intended valve placement site in the target airway.
4) Upon inflation, the balloon must contact the entire circumference of the target site for an entire breath cycle.
5) The volume of the balloon will serve as a reference for correlating the size of the airway with the valve size that will fit as designed.
6) Look up the syringe volume on the worksheet table and select the indicated valve.

NOTE If the inflated balloon is just touching the circumference of the target location and the syringe volume falls on a calibration volume, choose the larger size valve.

NOTE Over inflation may result in selecting a valve that is too large. Under inflation will result in selecting a valve that is too small.

7) Before retracting the balloon inside the bronchoscope, fully deflate the balloon by returning the plunger to the 500µL mark.

NOTE Do not pull the plunger beyond the 500 µL mark. If the plunger is pulled out, proceed to the next section for recovery steps. Do not reinsert the plunger while the syringe is still attached to the balloon. This will introduce excess air into the system which will affect the previous calibration.

8) If evaluating other airway locations, repeat steps 2 through 7.
9) When the targeted airways have been evaluated, withdraw the balloon catheter from the bronchoscope. Place the balloon catheter in a safe, clean area until the procedure is completed.
10) Proceed to place valves according to the instructions for the Valve in Cartridge and Deployment Catheter and Loader (see Instruction Manual for the Spiration Valve System).

8.4 Recovery from pulling the plunger out of the glass syringe

1) If the plunger for the glass syringe is accidentally pulled out, do not reinsert the plunger. Remove the balloon from the bronchoscope and disconnect the glass syringe from the stopcock.

NOTE Do not reinsert the plunger while the syringe is still attached to the balloon. This will introduce excess air into the system which will affect the previous calibration.

2) Repeat steps 12-15 and 17-18 of the section 8.1 "Preparing the Balloon Catheter."
3) Confirm that the CAL volume hasn't changed. If the volume has changed, complete section 8.2.
4) Fully deflate the balloon by returning the plunger to the 500µL mark.
5) Continue using the balloon to select valve sizes.

9. Patient Information

A Patient Information Pamphlet is available for potential patients (Patient Information for the Spiration Valve System, Humanitarian Device for Use in the Control of Air Leaks). Patients who receive treatment will be given a wallet card that indicates the patient has valve(s) and lists the procedure doctor's contact information.

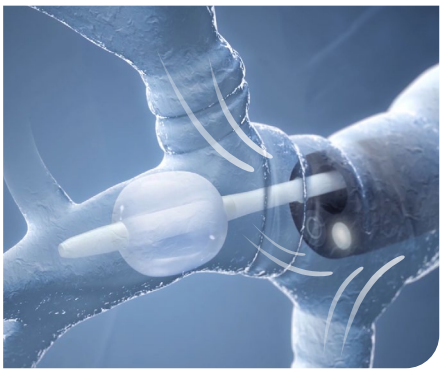
PI-05950 Rev AA

Spiration™ Valve System for Management of Air Leaks

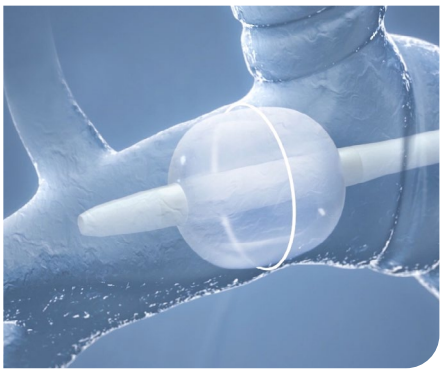
Supporting Documentation

F: Spiration Valve System Procedure Steps Overview

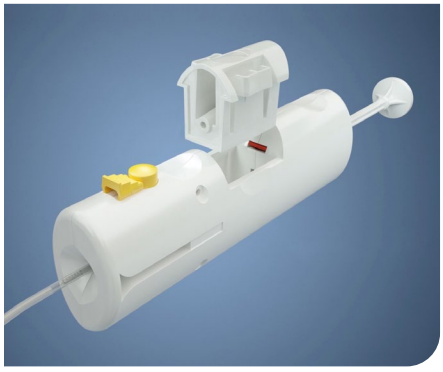
Balloon Calibration



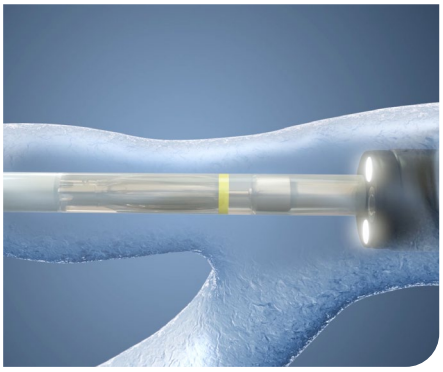
Airway Isolation



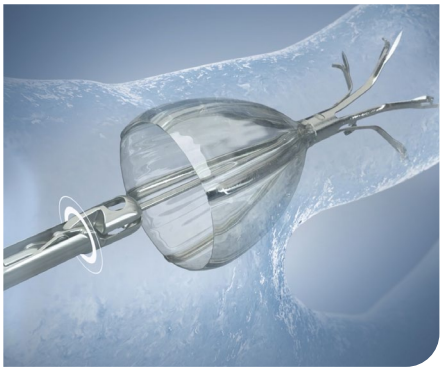
Airway Sizing



Valve Loading



Valve Placement



Valve Removal

Spiration™ Valve System for Management of Air Leaks

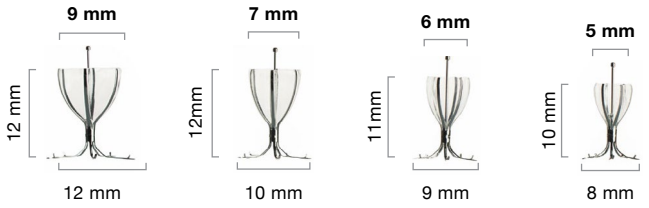
Please see important Spiration™ Valve System information on the next page.

Spiration™ Valve System

Spiration Valves

A single-use, one-way bronchial valve preloaded in a disposable cartridge.

Catalog Number	Valve in Cartridge
REF-HUS-V5	5 mm
REF-HUS-V6	6 mm
REF-HUS-V7	7 mm
REF-HUS-V9	9 mm



Airway Sizing Kit

A kit used to determine the appropriate valve size for each target airway.

Catalog Number	Kit Includes
REF-HUS-VSK	500 microliter glass syringe with a plunger, a calibration gauge, and a sizing worksheet **Note:** 1 Olympus B5-2C Disposable Balloon Catheter is shipped with each airway sizing kit

Deployment Catheter and Loader

A convenient deployment system for the delivery of multiple valves during a single patient procedure.

Catalog Number	Bronchoscope Working Channel	Deployment Catheter Length
REF-HUS-C26N	2.6 mm or greater inner diameter	1020 mm

Ancillary equipment needed for each procedure

- Flexible therapeutic bronchoscope with a working channel inner diameter of 2.6 mm or greater
- Bronchoscopy forceps appropriate for valve removal
- Standard 10cc sterile syringe with Luer-lock
- Sterile saline (approximately 15–30cc used per procedure)
- A balloon catheter that inflates to 13 mm or larger (for balloon occlusion only)

Note: Products are supplied sterile

For Customer Support:

Email: **HUD-customersupport@olympus.com**
Toll Free: **855-497-1616**
Fax: **425-999-4545**

To Request Technical Procedure Support:

Visit: **svs.olympusamerica.com/support**

For Reimbursement Support:

Toll Free: **877-205-1532**
Email: **Olympusunite@priahealthcare.com**

Disclaimer: The information presented here is for illustrative purposes only and does not constitute reimbursement or legal advice. The reimbursement information provided by Olympus America Inc. and/or its direct or indirect (through one or more intermediaries) parent companies, affiliates or subsidiaries (collectively, the "Olympus Group") is gathered from third-party sources and is subject to change without notice. Reimbursement rules vary widely by insurer so you should understand and comply with any specific rules that may be set by the patient's insurer. You must also understand and comply with Medicare's complex rules. It is the provider's sole responsibility to determine medical necessity and to in turn identify which CPT codes to report and to submit accurate claims. You should always consult with your local payers regarding reimbursement matters. Under no circumstances shall the Olympus Group or its employees, consultants, agents or representatives be liable for costs, expenses, losses, claims, liabilities or other damages (whether direct, indirect, special, incidental, consequential or otherwise) that may arise from or be incurred in connection with this information or any use thereof.

Coding recommendations, coverage policies, and reimbursement rates and methodologies vary by payer and are updated frequently. Providers should review applicable payer guidelines and instructions to ensure that billing practices comply with the payer's requirements and contact the payer if they have any questions. The American Medical Association (AMA) is responsible for development and maintenance of Current Procedural Terminology (CPT®) codes. Providers should check the complete AMA CPT reference manual and/or another authoritative source for a complete listing of all CPT codes and their descriptors. It is the provider's responsibility to report the code(s) that accurately describes the procedure(s) furnished and the patient's diagnosis. Please note that the presence of a code, or billing a particular code, is not a guarantee of payment. Reimbursement will vary for each provider based on a number of factors, including the payer, site of service, geographic location and contractual terms.

CAUTION: Humanitarian Use Device. Authorized by Federal law for use in the control of prolonged air leaks of the lung, or significant air leaks that are likely to become prolonged air leaks, following lobectomy, segmentectomy, or Lung Volume Reduction Surgery (LVRS). The effectiveness of this device for this use has not been demonstrated. Federal law restricts this device to sale by or on the order of a physician.

OLYMPUS AMERICA INC.
3500 Corporate Parkway, PO Box 610, Center Valley, PA 18034

For more information, contact your Olympus sales representative, or call 800-848-9024.
www.medical.olympusamerica.com

Printed in USA OAIRES0322BRO44100